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10/527,810	01/17/2006	Marc Schwaller	3493-0147PUS1	1921

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EXAMINER	
MCCORMICK, MELENIE LEE	

ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
01/31/2008	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

## Office Action Summary

Application No.

10/527,810

Applicant(s)

SCHWALLER, MARC

Examiner

Melenie McCormick

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5,8,9,11,12 and 14-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,8,9,11,12 and 14-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10 January 2007 has been entered.

Claims 6-7, 10, and 13 have been cancelled.

Claims 1-5, 8-9, 11-12, 14-25 are pending and presented for examination on the merits.

The previous rejection under 35 U.S.C. 112, second paragraph has been overcome by the claim amendments. The rejection is withdrawn.

The previous rejection under 35 U.S.C. 102(b) has been overcome by the amendment to claim 1, which now recites particular amounts of marrow oil and borage oil. The rejection has been withdrawn.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 recites 'Composition according to claim 7'. Because claim 7 has been cancelled, it is not clear which composition claim 21 is referring to.

***Claim Rejections - 35 USC § 103***

Claims 1- 3, 5, 9, 15, 20, 21 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deckers et al. for reasons discussed in the previous Office Action , which are presented and elaborated upon below (US 2002/0106337 A).

Deckers et al. teaches a composition which comprises oil bodies. Deckers et al. also discloses that the composition is useful for topical application to the human body (see e.g. [0002]). Deckers et al. further teach that the oil bodies are derived from plant seeds, including borage and squash (marrow), and that the composition may comprise mixtures thereof (see e.g. [0053]). This reads on a composition comprising borage oil and marrow oil in combination wherein the marrow oil is extracted from the marrow pips and/or the borage oil is extracted from borage seeds, as instantly claimed. As

evidenced by [encarta.msn.com](http://encarta.msn.com), pips are seeds (see e.g. [encarta.msn.com](http://encarta.msn.com)). Deckers et al. further teach that the composition may additionally comprise seed extract (oil) of soybean (see e.g. [0053]). Please note that the soybean oil extract would inherently contain isoflavones therein. Deckers et al. also disclose that the composition is formulated for topical application for improvement or benefit of the physical appearance, health, fitness or performance of the surface area of the human body (see e.g. [0039]). This reads on a medicinal product, a dermatological agent, a dermocosmetic agent, or a nutraceutical agent, as instantly claimed. Please note that although Deckers et al. teach the composition is formulated for topical application, nothing would preclude one from orally administering the composition, as recited in the instantly claimed intended use. This is true because the composition taught by Deckers et al. is essentially an oil body emulsion, which is free from contaminants (see e.g. [0045]). Deckers et al. also teach that the composition may be a toothpaste, which would be suitable for oral administration and reads on a paste as instantly claimed (see e.g. claim 32). Therefore the composition taught by Deckers et al. would be suitable for oral use. Deckers et al. do not explicitly teach that the composition is in the form of an oil or gel or that the amounts of borage or marrow or soybean oil are present in the particular amounts instantly claimed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a composition comprising borage and marrow seed oil and additionally comprising soybean seed oil, as instantly claimed. One of ordinary skill in the art at the time the claimed invention was made would have been

motivated and would have had a reasonable expectation of success in doing so based upon the disclosure of Deckers et al. that such a composition has been prepared and is useful for improvement or benefit of the physical appearance, health, fitness or performance or the surface area of the human body (see e.g. [0039]). The skilled artisan would have been motivated to formulate the composition such that it is suitable for oral administration, as Decker et al. discloses that the composition may be a toothpaste (see e.g. claim 32). Because Deckers et al. teach the composition comprises oil bodes (see e.g. abstract), the skilled artisan would be motivated to provide the composition in the form of an oil. In addition, because the composition may be used for a variety of personal care products, the skilled artisan would understand that a gel formulation would be beneficial (see e.g. abstract). This is particularly true of the toothpaste composition, as the skilled artisan would know toothpastes are commonly provided in gel form. A person of ordinary skill in the art would have had a reasonable expectation of success in adjusting the percentages by weight of borage, marrow and soybean oil of the composition because Deckers et al. teaches that the composition is used to improve or benefit the physical appearance, health, fitness, or performance of the surface area of the human body. Therefore, a person of ordinary skill in the art would recognize that the particular amount of the ingredients could be optimized in order to achieve the most useful composition for improving health, fitness, or performance of the surface area of the human body.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed

invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Response to Arguments***

Although Applicants have stated that the claims were rejected under 35 U.S.C. 103(a) as being unpatentable over Deckers US 6,146,645, the claims were actually rejected under 35 U.S.C. 103(a) as being unapentable over Deckers US 2002/0106337. The rejection over Deckers '337 is discussed above. Applicants have presented arguments for a 103(a) rejection over Deckers '645. There is no such rejection. A response is provided below with regard to the rejection over Deckers '337.

Applicants argue that because claim 1 has been amended to specify the amounts of marrow oil and borage oil, the rejection is overcome. This is not persuasive. As previously stated, a person of ordinary skill in the art would have had a reasonable expectation of success in adjusting the percentages by weight of borage, marrow and soybean oil of the composition because Deckers et al. teaches that the composition is used to improve or benefit the physical appearance, health, fitness, or performance of the surface area of the human body. Therefore, a person of ordinary skill in the art would recognize that the particular amount of the ingredients could be optimized in order to achieve the most useful composition for improving health, fitness, or performance of the surface area of the human body.

With regard to Applicants arguments that the prior art does recognize the unexpected advantageous properties achieved by the present invention as evidenced by the comparative result discussed, the results discussed are not unexpected. Applicants have pointed to the specification, particularly the table on page 13. This table presents result for the total number of hairs/cm<sup>2</sup> and the anagenic/ telogenic ratio. Group 1 received marrow oil only and experienced a 2.4% increase in total number of hairs/cm<sup>2</sup>. Group 2 received borage oil alone and experienced a 2.3% increase in total number of hairs/cm<sup>2</sup>. Group 5, which received borage oil and marrow oil together experienced a 3.4% increase in total number of hairs/cm<sup>2</sup>. Similarly, the anagenic/ telogenic ratio for Group 1 was increased 10.2%. The same ratio for Group 2 was increased 13.9. The ratio was increased by 20.5% for Group 5. This is not an unexpected result. A person of ordinary skill in the art would expect at least slightly higher results when two ingredients are combined than when the ingredients are used separately. Evidence of a greater than expected result may also be shown by demonstrating an effect which is greater than the sum of each of the effects taken separately (i.e., demonstrating "synergism") (MPEP 716.02(a)). Applicant's results for the combination of borage oil and marrow oil are less than the sum of the two ingredients results. Therefore, the results do not demonstrate synergism and do not demonstrate an unexpected result.

The rejection is therefore deemed proper and is maintained.



***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 8-9, and 11-12 and 14-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deckers et al. (US 6,146,645), Duranton et al. (US 6,465,421), Francis (US 5,695,748), and Segelman (US 6,017,893) for reasons set forth in the previous Office Action, which are discussed and elaborated upon below.

Deckers et al. (US 6,146,645) beneficially teach a composition for topical application which comprises soybean oil and/or cucurbita (marrow) oil, wherein the oil is obtained from seeds of the plant (see e.g. col 7, lines 35-46). Deckers et al. further teach that the composition is useful for combating hair loss and that the oil extract comprises 1-99% by weight of the composition (see e.g. col 14, lines 10-20). Deckers et al. also teach that the composition may be a food product (food composition or food supplement), a personal care product or a pharmaceutical product (nutraceutical agent) (see e.g. claim 25). Deckers et al. further teach that the composition may be a gum (see e.g. claim 26) or that it may be a cosmetic product, including, among other forms, a skin cream or a facial cream (which read on dermocosmetic/dermatological agent) (see e.g. claim 28).

Duranton et al. beneficially teach a composition which has hair growth-modulating properties (see e.g. col 1, lines 17-18). Duranton et al. further beneficially teach that the composition is intended to promote the growth of hair and that the composition contains borage oil (see e.g. claim 1). Duranton et al. also teach that the composition may be administered topically or orally (see e.g. col 6, lines 40-45).

Francis beneficially teaches a mixture (composition) which contains nettle and is used for restoring hair growth (see e.g. claim 1). It is further beneficially taught by Francis that the nettle can be in the form of a powder or a tea (which would be in a form suitable for oral administration) (see e.g. col 3, lines 13-16). Francis further teaches that the mixture is applied to the scalp (topical application) (see e.g. claim 1).

Segelman beneficially teaches a composition for preventing and treating hair loss (see e.g. col 1, lines 11-15). Segelman further beneficially teaches that the composition may be used topically or orally (see e.g. col 1, lines 60-65). It is further disclosed by Segelman that the composition is made from soybeans in powdered form and contains isoflavones (see e.g. col 7, example ii). Segelman also discloses that the topical forms of the composition include ointments, creams, lotions or other solutions, which read on a medicinal product, a dermatological agent, a dermocosmetic agent, or a nutraceutical agent (see e.g. col 6, lines 16-19). It is further disclosed by Segelman that the oral forms of the composition include capsules, tablets and powders (see e.g. col 6, lines 28-56).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit-

i.e. treating hair loss/alopecia -since each is well known in the art for the same purpose and for the following reasons. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose (as well as to use the combination for that purpose). The idea for combining them flows logically from their having been used individually in the prior art. In re Sussman, 1943 C.D. 518; In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). This rejection is based upon the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. It would further have been obvious to the skilled artisan to provide the composition in the form of a capsule, tablet, granule, paste, gum, oil, wafer capsule, gel capsule, chewing paste, oily jelly or food supplement, as each of the references beneficially teaches that the hair loss compositions comprising the instantly claimed extracts can be used orally or topically. The various forms instantly claimed well known in the art as typical oral or topical formulations, and therefore would have been obvious to one of ordinary skill in the art at the time the claimed invention was made. A person of ordinary skill in the art would have had a reasonable expectation of success in adjusting the particular result effective concentration of each component in order to achieve the best results. This is true because each of the components was known to have use in combating hair loss.

Therefore, a person of ordinary skill in the art would have been reasonably expected to optimize the result-effective amounts of each component in order to achieve the best results. In addition, a person of ordinary skill in the art would have had a reasonable expectation of success in using particular parts of the herb from which each extract is derived because these plants are all known to be useful for the same purpose.

Therefore, a person of ordinary skill in the art would have good reason to examine various parts of these known advantageous plants for therapeutic activity.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Response to Arguments***

Applicants argue that Duranton, Francis, and Segelman not disclose marrow oil. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The Deckers '645 reference was relied upon for the teaching of marrow oil. Applicants further argue that the references do not teach the specific amount of marrow oil recited in claim 1. As previously stated, a person of ordinary skill in the art would have been

motivated and would have had a reasonable expectation of success in adjusting the result-effective amount of the ingredients instantly claimed because they were all known to combat hair loss. In particular, Deckers '645 teaches a composition which comprises soybean oil and/or cucurbita (marrow) oil, wherein the oil is obtained from seeds of the plant (see e.g. col 7, lines 35-46) and that the composition is useful for combating hair loss and that the oil extract comprises 1-99% by weight of the composition (see e.g. col 14, lines 10-20). In addition, Duranton et al. teaches a method for promoting hair loss using the active ingredient borage oil, Francis teaches a mixture (composition) which contains nettle and is used for restoring hair growth (see e.g. claim 1), and Segelman teaches a composition for preventing and treating hair loss (see e.g. col 1, lines 11-15) and that the composition is made from soybeans in powdered form and contains isoflavones (see e.g. col 7, example ii). Therefore, a person of ordinary skill in the art would have had good reason to optimize the amounts of each of the instantly claimed ingredients in order to achieve the most effective hair loss combative results.

Applicants further argue that there seems to be no suggestion from one skilled in the art to combine the selected components from Deckers '645 with any of Duranton, Francis, and Segleman. Because each of the references teaches the instantly claimed ingredients is useful for the same purpose, a person of ordinary skill in the art would have had a reasonable expectation of success in combining them for that same purpose.

Applicants also argue that Decker's fails to mention the presence of borage oil. As previously stated, one cannot show nonobviousness by attacking references

individually where the rejections are based on combinations of references. Durantoni was relied upon for the teaching of borage oil. Applicants also argue that the references fail to provide a suggestion regarding the unexpected, advantageous results evidenced by the instant specification. As discussed above, the results provided in table 1 are not unexpected or synergistic results. Therefore, it would have been obvious to a person of ordinary skill in the art to combine and use the instantly claimed ingredients for their known benefit in combating hair loss.

The rejection is therefore deemed proper and is maintained.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melenie McCormick whose telephone number is (571) 272-8037. The examiner can normally be reached on M-F 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Melenie McCormick  
Examiner  
Art Unit 1655



CHRISTOPHER R. TATE  
PRIMARY EXAMINER